

Message Text

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PAGE 01 STATE 128776
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 /023 R

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APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OIH:RBUHRICH, M.D.
EA/J:RCHRISTENSON(INFO)

-----040201Z 065656 /70

P 032207Z JUN 77
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY

UNCLAS STATE 128776

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, JA

SUBJECT: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE
RECALL T-112-7

1. FDA ADVISES OF THE FOLLOWING DEFECTIVE DEVICE:

PRODUCT INVOLVED: CASTLE SURGICAL TABLE (MODEL T-5000) WITH
SCHOLZ IMAGE INTENSIFICATION TOP. THE SCHOLZ IMAGE INTEN-
SIFICATION TOP (SCHOLZ SURGICAL TOP, SYSTEM 1564) IS
ATTACHED ATOP THE SURGICAL TABLE FOR USE IN TAKING X-RAYS
OF PATIENT.

PRODUCT IDENTIFICATION: (A) SURGICAL TABLE-CASTLE CO., MODEL
T-5000, FIVE SECTION - ADJUSTABLE OPERATING TABLE. (B)
IMAGE INTENSIFICATION TOP-FLAT SURGACED BOARD, BLACK IN COLOR
APPROX. 60 INCH LONG X 20 INCH WIDE X 3/4 INCH THICK. ON
ONE END IS TWO METAL HOOKS FOR ATTACHING IT TO THE TABLE.
APPROX. 12 INCHES DOWN THE BOARD, ON EACH SIDE, IS A SPUR
WHICH WHEN IN PLACE HOLDS THE TOP IN PROPER ALIGNMENT ON THE
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TABLE. ON THE UNDERSIDE OF THE TOP IS A LABEL READING IN
PART, "MODEL 1564 SER.NO. XXX CODE XXX FRANK SCHOLZ X-RAY
CORP. NEEDHAM HEIGHTS, MA. 02194". LABEL IS APPROX. 1 INCH
BY 3 INCHES IN SIZE.

MANUFACTURER:

(A) TABLE: CASTLE CO.-DIV. SYBRON CORP.
1777 E. HENRIETTA ROAD
ROCHESTER, NEW YORK 14623

(B) TOP: FRANK SCHOLZ X-RAY CORP.
P O BOX 223
NEEDHAM HEIGHTS, MASS 02194

RECALLING FIRM: CASTLE CO.-DIV. SYBRON CORP.
1777 E. HENRIETTA ROAD
ROCHESTER, NEW YORK 14623

REASON FOR RECALL: CASTLE CO. WAS NOTIFIED IN OCT. 1976 THAT DURING USE ON ONE OF THEIR MODEL T-5000 SURGICAL TABLE ONE OF THE HOOKS ON THE TOP BEING USED BROKE. NO INJURY WAS REPORTED. THE COMPLAINANT'S DESCRIPTION OF THE INCIDENT DISCLOSED THAT THE TABLE WAS USED IMPROPERLY AT THE TIME. THE SECTION OF THE TABLE SUPPORTING THE SPURS OF THE TOP WAS LOWERED, CAUSING EXTRA STRAIN ON THE HOOKS. UNDER THIS EXTRA STRAIN ONE OF THE HOOKS BROKE. CASTLE CO. WAS ABLE TO RECONSTRUCT THE INCIDENT AT THEIR LABORATORY BY FOLLOWING THE STEPS DESCRIBED BY THE COMPLAINANT. FIRM DETERMINED THAT CORRECTIVE ACTION SHOULD BE TAKEN.

2. POST REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THEY HAVE BEEN ADVISED OF CORRECTIVE ACTION REQUIRED. THE FIRM WILL AFFIX CAUTION LABEL TO (1) THE CONTROL UNIT OF THE TABLE (2) THE SURFACE OF THE TOP. INSTRUCTIONS FOR USE WILL BE CHANGED IN THAT PLACEMENT OF UNCLASSIFIED

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THE TOP ON THE TABLE WILL BE CHANGED SO THAT THE EXCESS STRAIN WILL NOT BE ON THE HOOKS EVEN IF THE TABLE IS OPERATED IMPROPERLY.

NEW HOOKS HAVE BEEN DEVELOPED BY FRANK SCHOLZ X-RAY CORP. THE NEW HOOKS ARE MADE OF STEEL INSTEAD OF ALUMINUM AND ARE ALSO HEAVIER THAN THE ORIGINAL ONES. NEW HOOKS WILL BE INSTALLED ON ALL OF THE TOPS LOCATED.

3. FOREIGN CONSIGNEE AS FOLLOWS:

FUTABA KI KAI CO., LTD.
FUJIMAE BUILDING
NO. 27-16, 2, CHOME
HONKOME GONE
BUNKYO-KU
TOKYO JAPAN CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 03-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE128776
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770199-0433
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770691/aaaadccw.tel
Line Count: 114
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Litigation Codes:
Litigation History:
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Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2282082
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE RECALL T-112-7
TAGS: OGEN, ETRD, EIND, TBIO, JA
To: TOKYO
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/9da64685-c288-dd11-92da-001cc4696bcc
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